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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
WRIGHT, SONYA N	

ART UNIT	PAPER NUMBER
1626	

DATE MAILED: 02/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/913,373	BEATCH ET AL.	
	Examiner	Art Unit	
	Sonya Wright	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 5-85* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6,7,68 and 69* is/are rejected.

7)☒ Claim(s) *1-3,5,8-67 and 70-85* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-3 and 5-83 are pending in this Office Action. The rejection to claims for containing non-elected subject matter has been maintained. The rejection of claims 6 and 7 under 35 U.S.C. 101 and 35 U.S.C. 112 has been maintained.

Claim Objections

Claims 1-3 and 5-85 are objected to as containing non-elected subject matter. This objection may be overcome by limiting the claims to the elected subject matter identified in the previous Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6, 7, 68 and 69 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1404 (CAFC, 1988)):

1) Nature of invention.

2) State of prior art.

3) Level of ordinary skill in the art.

4) Level of predictability in the art

5) Amount of direction and guidance provided by the inventor.

6) Existence of working examples.

7)Breadth of claims.

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

See below:

1) Nature of the invention.

Claims 6 and 7 are drawn to a method for modulating ion channel activity. Claims 68 and 69 are drawn to treating autoimmune disorders in a warm-blooded animal.

2) State of the prior art.

The prior arts do not indicate what diseases the instant compound can be used to treat which involve modulating ion channel activity. The prior arts do not indicate which "autoimmune disorders" can be treated by the instant compound.

3) Level of ordinary skill in the art.

The level of skill in the art is high. Due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by in vitro and in vivo screening to determine which compounds exhibit the desired pharmacological activity and which diseases would benefit from this activity.

Thus, the specification fails to provide sufficient support of the broad use of the compound of the claim 1 for treating all diseases pertaining to modulating ion channel activity and autoimmune disorders.

Genentech Inc. v. Novo Nordisk A/S (CAFC) 42 USPQ2d 1001 , states that " a patent is not a hunting license. It is not a reward for search , but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

4) Level of predictability in the art.

The instant claimed invention is highly unpredictable as discussed below:

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. Hence, in the absence of a showing of treatment of all diseases related to modulating ion channel activity and autoimmune disorders by the compound of claim 1, one of skill in the art is unable to fully predict possible results from the administration of the compound of claim 1 due to the unpredictability of the art pertaining to modulating ion channel activity and autoimmune disorders.

The nature of pharmaceutical arts is that it involves screening *in vitro* and *in vivo* to determine which compounds exhibit the desired pharmacological activities. There is no absolute predictability even in view of the seemingly high level of skill in the art. The

existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face.

5) Amount of direction and guidance provided by the inventor.

The specification provides little guidance regarding the use of the instant compound in treating diseases related to modulating ion channel activity and autoimmune disorders. Applicant briefly mentions that the instant compound is useful in modulating the activity of ion channels in page 26, lines 21-33. Applicant briefly mentions that the instant compound is treating autoimmune disorders, for example, on page 5, line 14.

Applicant does not provide evidence that the instant compound is useful in treating all diseases related to ion channel activity and all autoimmune disorders. The guidance is limited because various diseases related to ion channel activity and the various forms of autoimmune disorders have different causative agents, involve different cellular mechanisms, and, consequently, differ in treatment protocol.

6) Existence of working examples.

The specification provides limited working examples that do not support that the instant compound is useful in treating all diseases related to ion channel activity and all autoimmune disorders. Applicant provides Examples 3-5 on pages 35-38.

7) Breadth of claims.

Claims 68 and 69 are extremely broad due to the phrase "modulating ion channel activity" and the terms "autoimmune diseases". One cannot determine the metes and bounds of the claims.

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Based on the unpredictable nature of the invention and state of the prior art and the extreme breadth of the claims, one skilled in the art could not use the claimed invention without undue experimentation.

In view of the Wands factors and In re Fisher (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test how the instant compound is useful in treating diseases related to modulating ion channel activity and in the treatment of autoimmune disorders, with no assurance of success.

These rejections can be overcome by Applicant listing in claims 6 and 7 which diseases related to modulating ion channel activity can be treated by the instant compounds and by Applicant listing in claims 68 and 69 which autoimmune disorders can be treated by the instant compounds. Any diseases and autoimmune disorders which are listed in claims 6, 7, 68 and 69 should be supported in the specification.

Response to Arguments

Applicant's arguments filed 11-7-03 have been fully considered. Applicant requests clarification of the status of the claims following the May 7, 2003 Office Action. Following the May 7, 2003 Office Action, claims 1-3 and 5-85 were objected to for

containing non-elected subject matter. (Claims 2, 3, and 5-85 were objected to because they depend from claim 1, which was objected to.) Claims 2 and 4-7, 5, 8-71, and 74-83 were rejected. The Examiner regrets any inconvenience by the previous Office Action Summary.

In the Office Action Summary attached herein, Applicant will note that the present status of the claims is that claims 6, 7, 68, and 69 are rejected and claims 1-3, 5, 8-67 and 70-85 are objected to.

Regarding the objection to claimed subject matter. Applicant argues that the Examiner's application of 37 CFR 1.142(b) is not appropriate. Applicant argues that because the compounds in the claim 1 Markush group possess a common utility and share a significant common structural element, unity of invention is present.

Applicant's argument that the application of 37 CFR 1.142(b) is not appropriate has been found persuasive. However, the restriction requirement has been maintained for the following reasons. The claims herein lack unity of invention under PCT Rule 13.1 and 13.2 since the compounds defined in the claims lack a significant structural element qualifying as the special technical feature that defines a contribution over the prior art. The compounds claimed contain a core which is a cycloalkyl group with a nitrogen substituent. Said core does not define a contribution over the art. Further, the cycloalkyl in the core contains substituents A, X, Q, R1, R2, R3, R4, R5, R6, R7, R8, R9, R13, etc. . .. The substituents on the cycloalkyl group vary extensively and when taken as a whole result in vastly different compounds. Accordingly, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of

unity of invention is considered to be proper. Moreover to not restrict herein, would impose a burden on the examination of this application.

Regarding the rejection to claims under 35 U.S.C. 101, Applicants argue that they have cancelled claim 4 and have amended claims 5-7 to include the steps of the claimed methods. However, claim 6 and 7 are drawn to a mechanism and Applicant has not provided an intended use. Due to Applicant's amendment, the claims have been rejected under 35 U.S.C. 112 first paragraph.

The rejections of claims 2 and 5 under 35 U.S.C. 112 have been overcome with Applicants' amendments.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sonya Wright, whose telephone number is (703) 308-4539. The examiner can normally be reached on Monday-Friday from 8:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (703) 308-4537. The Unofficial fax phone number for this Group is (703) 308-7922. The Official fax phone numbers for this Group are (703) 308-4556 or 305-3592.

When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-1235.

Joseph K. McKane

Supervisory Patent Examiner

Group 1600

Sonya Wright

January 15, 2004